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10/670,168	09/25/2003	Gil M. Vardi	1001.2278101	2222

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	PAPER NUMBER
3731	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,168	VARDI ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8,28-30 and 32-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,8,28-30 and 32-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. For the record, claims 4, 7, 17 and 22 claim subject matter that does not have support in the parent case (09/860,744), therefore they will not receive the benefit of the earlier filing date.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the main guidewire port and the branch guidewire port being located at different locations must be shown or the feature(s) canceled from the claim(s). Note that claim 5 recites that the main guidewire port is positioned between 10 and 50 cm from the distal end while claim 1 indicates that the branch guidewire exit port can be located more than 100 cm from the distal end. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 4, 5, 8, 28-30, 32-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claim 1 recites that the "intermediate region of the branch guidewire enclosure is at least 10 cm to 100 cm in length”. There is no disclosure in the specification as to what constitutes the intermediate region or its length, thus there is no way for one of skill in the art to know what delineates the intermediate region or how to measure it. Rather the specification defines the length of the *shaft* (not the length of the intermediate region) from the bond to the balloon as 1-100 cm and preferably around 10 cm or more. Note

that the length of the shaft from the bond to the balloon not only includes the intermediate region but also includes the proximal region and could also possibly include the distal region. Thus the claim as written encompasses a scope greater than that which is described by the original disclosure (i.e. a shaft that could be more than 100 cm. from the balloon to the bond).

6. Claim 8 recites that the branch guidewire exit port is positioned between 50 and 150 cm from the distal end of the catheter. Claim 1 recites that the branch guidewire exit port is positioned distal of the proximal end of the catheter. The specification discloses the branch guidewire exit port being located between 50 and 150 cm from the distal end, but only with respect to an embodiment where the enclosure extends to the proximal end of the catheter. Thus there is no support for a branch guidewire exit port being distal of the proximal end of the catheter *and* positioned between 50 and 150 cm from the distal end of the catheter.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 4, 5, 8, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 recites that the “guidewire enclosure is at least 10cm to 100 cm", It is unclear if: A) the “at least” applies to the entirety of the range such that the lower limit

(at least) is anywhere from 10 to 100cm and there is no upper limit; or B.) the “at least" applies to only the lower limit value of 10 cm. with the upper limit value of 100. In the case of the latter, it is not clear why the limitation "at least" would be needed to apply to the lower limit in a closed range.

10. Claim 30 recites that the first and second guidewires are less than 50 cm. However the bond at the proximal end region (and thus the open end of the tube that defines the second guidewire port) is spaced from the balloon by around 10cm to 100cm. It is unclear how the guidewires can be less than 50 cm if the port can be distanced from the distal end by more than 50 cm.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 4, 5, 8, 28-30, 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (US 6,273,879) in view of Adams (US 6,099,497) and further in view of Sirhan (US 5,743,875)

13. Keith discloses a catheter system comprising: a catheter including a proximal end and a distal end, the catheter comprising: a first tubular member/first catheter (for example 22 and 24; C5:L33-40), including a proximal end (for example near 28) and a

distal end (34), the first tubular member defining an inflation lumen (62 and 104) of the catheter and extending distally from the proximal end of the catheter; a second tubular member/first distal tube (80) defining a main guidewire lumen (52), wherein the distal end (90) of the second tubular member is a distal end of the catheter and the proximal end of the second tubular member has a proximal end region (84) defining a proximal open end/main guidewire exit port (92), wherein the main guidewire lumen is configured to receive a main vessel guidewire therethrough (C7:L31-35), wherein the second tubular member is at least partially disposed within the inflation lumen of the first tubular member (Fig 2; C7:L12-21); a balloon (26) including a proximal waist (36) coupled to the first tubular member adjacent to the distal end of the first tubular member and a distal waist (40) coupled to the second tubular member adjacent to the distal end of the second tubular member (C8:L3-16). The proximal end of the first distal tube is disposed at or near the intermediate region of the first catheter tube (see for example Fig. 1, 2) and remains open to define a first guidewire exit port (92). The first distal tube is at least partially attached to the first catheter tube and at least partially disposed within the first catheter tube (see Fig. 1).

14. Keith does not disclose a branch guidewire enclosure or a stent. However, Adams discloses a balloon catheter that is designed to accommodate delivering a stent to an ostium or bifurcation. Adams incorporates a two guidewire system using two separate guidewire lumens which is well known in the art for (see for example 136 in any of figs. 14a-18). In particular a branch guidewire enclosure/second distal tube (for example 166, 172 or 182) positioned alongside the first tubular member, wherein the

branch guidewire enclosure defines a lumen (136) configured to receive a branch vessel guidewire therethrough (C10:L9-17), the branch guidewire enclosure including a proximal end region having a proximal end and a distal end region (see Fig. 17 and 18 and C10:L9-24), the proximal end of the branch guidewire enclosure defining a branch guidewire exit port (C10:L18-23 where the location of the port is considered to be the proximal end of the branch guidewire enclosure since the guidewire exits at the port and beyond the port, there would no longer be a guidewire enclosure), and a stent (For example Fig.7a, 64) having a lumen and a side opening (68) in a wall thereof, the stent positioned about at least a portion of the balloon, and wherein a distal portion of the branch guidewire enclosure is positioned through the lumen of the stent (C11:L24-30) and exits at the side opening; wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter (C10:L18-23). With respect to the branch guidewire enclosure bonded only to the first tubular member at a bond at the proximal end region, it is noted that the *proximal end region* has no defined limits and therefore the portion where the branch guidewire enclosure is bond to the tubular member is considered the proximal end region (see for example Fig. 17 which shows that the entire enclosure is not bonded). The main guidewire exit port and the branch guidewire exit port are located substantially at the same longitudinal distance along the catheter (as understood by C10:L18-23). The second distal tube is detached from the first distal tube outside of the bond and the second distal tube does not include a balloon (see Fig. 18 and C12:L30-43).

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the balloon of Keith in order that it is capable of delivering a stent. It is well known in the art to use catheters similarly structure to Keith for delivering stents and so it would be well within the skill of the ordinary artisan to use the balloon for stent delivery. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a branch guidewire enclosure to the balloon such that the device would be capable of delivering a stent to an ostium or bifurcation. Doing so would allow the user to precisely deliver a stent to an ostium or a bifurcation. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the guidewire structure such that it is bonded to the first tubular member of Keith since the first tubular member is the outermost surface of the catheter.

16. Modified Keith discloses that the branch guidewire enclosure has a proximal end region and a distal end region but does not explicitly disclose an intermediate region of at least (around) 10 cm to 100 cm in length disposed between the balloon and the bond. Modified Keith does not explicitly disclose that the main guidewire exit port is positioned between 10 and 50 centimeters from the distal end of the catheter or that the branch guidewire exit port is located between 50 and 150 centimeters from the distal end of the catheter. However Adams does disclose that the length of the branch enclosure which typically defines the distal tip in the intermediate region of the balloon could be made longer such that its distal tip resides in the branch vessel (C12:L36-42). Further, Sirhan discloses a balloon catheter having a guidewire exit port located at between 5 cm and 45 cm from the distal end of the catheter. Thus based on the teachings of Adams and

Sirhan, it would have been well within the skill of the ordinary artisan to modify the length of the intermediate portion of the branch guidewire portion and the distance of the guidewire ports in order to suit the particular needs of the user in terms of where and how the device is intended to be used in the body. One of skill is able to pursue known options within his or her technical grasp if it yields predictable results, namely a way of varying the location of the ports to accommodate various locations in the body.

17. With respect to claim 4: Klein discloses a bonding material coupling the first tubular member and the second tubular member (C7:L22-30). It would have been obvious to one having ordinary skill in the art at the time of the invention to use a similar bonding material to couple the branch guidewire enclosure to device. Since the guidewire port would necessarily need to be bonded or coupled in some manner, it is common sense to do it in the same manner that other elements of the device are being coupled or bonded.

18. With respect to claim 30, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the length of the guidewire in light of the modifications with respect to location of the exit port. It is well known in the art to modify dimension to suit the intended use of the device for example size of the patient or location of the body being treated.

Response to Arguments

19. Applicant's arguments filed 06/07/11 have been fully considered but they are not persuasive. Applicant states that Keith does not disclose a balloon with a proximal waist

coupled to the first tubular member distal end. Rather Applicant presents that Keith discloses a tubular member that has a distal end (30) that is not coupled to the balloon and an intermediate sleeve (24) that is coupled to the balloon. However, there is nothing that precludes examiner from calling the combination of 22/66/24 the tubular member. All three components are coupled in such a way that they form the inflation lumen. It is irrelevant whether the tube is a single unitary piece of material or three pieces of material joined together as long as the structure reads on the claimed limitation. Further there is nothing that requires the balloon be directly in contact with the distal end of the tubular member. As such the balloon can be considered to be coupled (indirectly to any portions of elements 22/66/24.

20. Applicant states that none of the references specifically teach bonding the branch guidewire enclosure to the tubular member only at a bond at the proximal end region. As noted above, the limitation “proximal end region” can be read very broadly since there is no definition as to what delineates the “proximal end region”. As such, examiner asserts that where ever the bond is located would be considered the proximal end region.

Applicant asserts that the motivation to modify the length of the guidewire enclosure to achieve the claimed structure appears to be based on the present specification. Examiner respectfully asserts that modifying the size of a medical device to accommodate differently sized patients or different locations in the body has been long well known in the art prior to applicant’s disclosure. The teachings of the references provide the options that are known in the art at the time of the invention and available to

one of skill in the art. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

21. Note, that while examiner erred in listing all the rejected claims in the introductory rejection statement, the essence of the claims has been encompassed in the body of the rejection. Further note that any changes in the rejection were a result of the amendments to the claims.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is

(571) 272-7134. The examiner can normally be reached on Monday – Friday from 9:00am to 5:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, TOM HUGHES, at* (571) 272-4357**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth Houston/
Primary Examiner, Art Unit 3731
08/14/11